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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,334	10/27/2005	Mikhail I Papisov	0492479-0041	1459
24280 7590 07/15/2009 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110				
EXAMINER CHU, YONG LIANG				
ART UNIT 1626		PAPER NUMBER		
NOTIFICATION DATE 07/15/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary**Application No.**

10/521,334

Applicant(s)

PAPISOV ET AL.

Examiner

YONG CHU

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11, 12, 14, 19, 20, 32-51, 54-56, 58 and 59 is/are pending in the application.
- 4a) Of the above claim(s) 32-40, 44-51, 54-56, 58 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-12, 14, 19-20, and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/24/2009 has been entered. Upon entering the submission, claims 1-6, 11-12, 14, 19-20, 32-51, 54-56, 58 and 59 are currently pending, claims 32-40, 44-51, 54-56, 58 and 59 remain withdrawn as non-elected subject matter. Claims 1-6, 11-12, 14, 19-20, and 41-43 are under examination on the merits.

Response to RCE Submission

Rejection of claims 1-12, 14, 19-22 and 41-43 under 35 U.S.C. §103(a)

Applicants' amendment and arguments have been fully considered, but not sufficient to overcome the rejection.

The present claims are drawn to biodegradable biocompatible polyacetals or polyketals conjugated to modifiers via oxime linkages. Applicants argue that the application of the Cervigni methods to the polyacetals of the '398 patent would not achieve the claimed invention, because the biodegradable biocompatible polyacetal exemplified by the '398 patent is PHF, which is pH-dependent. Cervigni exemplifies very harsh (*i.e.* pH 3 for 120 hours) conditions for conjugation that would cause nearly complete hydrolysis of the PHF main chain. This argument is not persuasive. The

harsh reaction condition for forming the oxime bond in the Scheme 2 is required specifically for making a saccharide-oxime-peptide conjugate, due to the conversion of saccharide hemiacetyl to saccharide aldehyde in the starting material of the saccharide

6. This harsh condition is not the only pH condition taught by the Cervigni methods. At page 1230, column 2, lines 1-6 of the reference, Cervigni specifically taught "an oxime bond is formed regioselectively under mild aqueous conditions in a one-pot reaction." In addition, at the same page, column 1, third paragraph, the reference 8 is provided for making oxime bonds. See *K. Rose, J. Am. Chem. Soc. 1994, 116, 30-33*. Specifically, at page 33 of the reference, an oxime formation is carried out at pH 4.6 at 22 °C. Even though the oxime bond is used to link to peptides at the both end, the reaction condition matter for making oxime bond is only related to a reaction of an aldehyde group and an amino-oxy group (*i.e.* $-\text{CHO} + -\text{O}-\text{NH}_2$ to $-\text{CH}=\text{N}-\text{O}-$). Therefore, the instant claims would be obvious over the Cervigni teaching in view of the '398 patent. The Office has established *prima facie* obviousness case, and the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art (e.g. unexpected results).

Conclusion

No claim is allowed.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu, Ph.D., whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M²Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu/
Patent Examiner
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